

Results report

1. Title of Research and Development : Development and sustainability of Malaria Vaccine Clinical Research Center
2. Principal Investigator : Tohihiro Horii (Osaka University, Professor)
3. Counterpart Principal investigator: Emanuel Odongo-Aginya (Gulu University, Associate Professor, Uganda)
4. Results of Research and Development:

The purpose of this research and development is to carry out higher order clinical trials of BK-SE36 malaria vaccine and to form a research base for the clinical basic research that is required for comprehensive malaria control. RIMD, Osaka University and Guru University School of Medicine are collaborating to form a clinical research center. From 2015 it is expanding its activities to Burkina Faso as well as Uganda.

Osaka University

(1) Collaborating with European Vaccine Initiative and the Burkina Faso National Malaria Research Center, Phase Ib BK-SE36 malaria vaccine clinical trial with 1-5-year-old infants (108 people) were commenced in June, 2015 in Banfora of Burkina Faso. It is currently steadily implemented. This trial is expected to end in 2016 fiscal year. (2) Artemisinin combination therapy (ACT) is considered as the ultimate weapon in malaria control at present. To investigate the emergence of drug-resistant parasites in Uganda, the isolated parasites from patient were subjected to drug resistant study against artemisinin and lumefantrine. As a result, most of the parasites showed over ten times resistant against both of drugs. (Collaborator; Juntendo University School of Medicine, Prof. Mita Toshihiro) (3) For the rapid and ultra-high-sensitivity malaria diagnostic device development, more compact (about commercial mobile PC) with battery-drive diagnostic device has developed. (Collaborators: National Institute of Advanced Industrial Science and Technology Shikoku Center, Project leader, Masatoshi Kataoka) (4) RAPID (Robotics Assisted Pathogen Identification System) by next-generation sequencing is standing by for unknown pathogens search in northern Uganda where emerging infectious diseases and rare disease are frequently emerged. For training, Dr. Richard Echodu, Gulu University was invited to Osaka University for 10 days.

Ehime University

For exploring novel malaria vaccine candidate antigens, 1827 proteins array of *Plasmodium falciparum* were subjected to 66 Ugandan serum samples and 9 vaccine candidate proteins were identified. From 2013, 3 young Ugandan researchers were admitted in Ehime University. They presented their research work at ASTMH 64th annual meeting in USA. All of them will graduate PhD course in the current fiscal year.

Gunnma University

Immune response to the vaccine is greatly influenced by the host state of infections. To clarify the relationship of environmental factors, DNA was extracted from fecal samples collected at Lacor hospital and subjected to the analysis with the next generation sequencers. In severe patients and mild patients, a significant difference was observed in the distribution of the intestinal bacteria. Further, it was found that G-CSF, and MPO such as neutrophils differentiation and related functions has increased in accordance with the condition in the analysis of inflammatory substances using HQPLEX plasma samples.